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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/553,554

10/18/2005

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210 7590 01/05/2010
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EXAMINER

STOCKTON, LAURA LYNNE

ART UNIT

PAPER NUMBER

1626

MAIL DATE

DELIVERY MODE

01/05/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/553,554	Applicant(s) CHAKRAVARTY ET AL.	
	Examiner Laura L. Stockton	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 July 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 8-12, 17 and 19-31 is/are pending in the application.
- 4a) Of the above claim(s) 19-31 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 11 and 12 is/are allowed.
- 6) ☒ Claim(s) 1,2,8-10 and 17 is/are rejected.
- 7) ☒ Claim(s) 3 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>June 17, 2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-3, 8-12, 17 and 19-31 are pending in the application.

Election/Restrictions

Applicant's election with traverse of Group I (claims 1-3, 8-12, 17 and 18 - drawn to products of Formula (I) wherein HET is a thiazole ring) in the reply filed on August 18, 2008 was acknowledged in the previous Office Action. The requirement was deemed proper and therefore made FINAL in the previous Office Action.

Subject matter not embraced by Group I and Claims 4-7, 13-16 and 19-31 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the

reply filed on August 18, 2008. Claims 4-7 and 13-16 have been cancelled per the Amendment filed July 1, 2009.

Information Disclosure Statement

The Examiner has considered the Information Disclosure Statement filed on June 17, 2009.

Oath/Declaration

The Declaration fails to comply with 37 CFR 1.497(a) (2) since PCT/US04/11271 is not identified in the Declaration.

Response to Arguments

Applicant's arguments filed January 14, 2009, and a duplicate on March 4, 2009, have been fully considered but they are not persuasive. Applicant argues that the

Declaration complies with 37 CFR 1.497(a)(2) since the Attorney Docket number is found in the top left-hand corner of the Declaration.

In response, the instant application is a 371 of PCT/US04/11271. Applicant has filed a Preliminary Amendment on October 18, 2005 to amend the instant specification to reflect that the instant application is a 371 of PCT/US04/11271. However, Applicant has failed to identify the PCT or make a claim for benefit in the Declaration filed October 18, 2005. Further, an application data sheet has not been filed in the instant application.

Rejections made in the previous Office Action that do not appear below have been overcome by Applicant's amendments to the claims. Therefore, arguments pertaining to these rejections will not be addressed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Oballa et al. {WO 2001/49288}.

Oballa et al. disclose, for example, the compound on page 17, lines 29-30, which is embraced by the currently amended claims. Therefore, Oballa et al. anticipate the instant claimed invention.

Response to Arguments

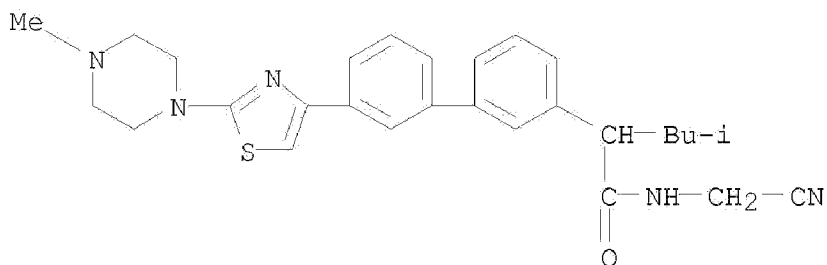
Applicant's arguments filed January 14, 2009, and a duplicate on March 4, 2009, have been fully considered

but they are not persuasive. Applicant argues that the instant claims have been amended to require that one of R^6 , R^7 and R^8 has to be other than hydrogen and therefore, the compounds in Oballa et al. do not anticipate the instant currently amended claimed compounds.

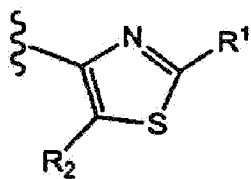
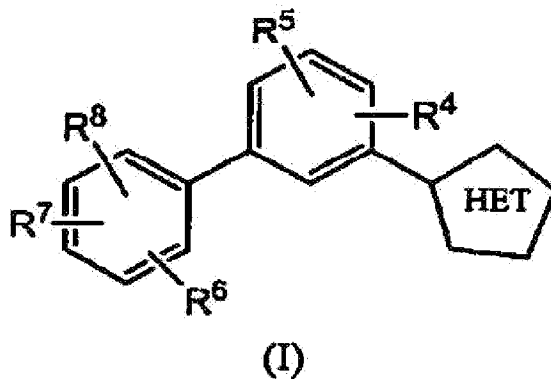
In response, it is disagreed that the currently amended claims are not anticipated by Oballa et al. See, for example, the compound on page 17, lines 29-30, of Oballa et al. (reproduced below as well as a structural depiction).

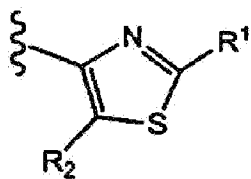
**4-Methyl-2-(3'-[2-(4-methyl-piperazin-1-yl)-thiazol-4-yl]-biphenyl-3-yl)-pentanoic
30 acid cyanomethyl-amide;**

RN 349669-89-2 CAPLUS
CN [1,1'-Biphenyl]-3-acetamide, N-(cyanomethyl)-3'-[2-(4-methyl-1-piperazinyl)-4-thiazolyl]- α -(2-methylpropyl)- (CA INDEX NAME)



The compound on page 17, lines 29-30, of Oballa et al.
is embraced by the currently amended claims of
Formula (I)



when **HET** is , R¹ is 4-substituted
piperazine-1-yl substituted with alkyl {definition (p)
substituted with definition iii)}; R², R⁴, R⁵, R⁷ and R⁸

are each hydrogen; and R^6 is C_1-C_6 -alkyl substituted with $CONR^aR^b$; R^a is hydrogen; and R^b is C_1-C_6 -alkyl substituted with CN. The rejection is deemed proper and therefore, the rejection is maintained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 8-10 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oballa et al. {WO 2001/49288} and Pick et al. {U.S. Pat. 5,462,959}, each taken alone or in combination with each other since similar utilities are asserted.

***Determination of the scope and content of the prior art (MPEP
§2141.01)***

Applicant claims thiazole compounds. **Oballa et al.** (see entire document; particularly pages 2-5, 36, 37, 107, 109, 118, 120, 122, 125 and 126; and especially the compound on page 17, lines 29-30) and **Pick et al.** (see entire document; particularly columns 1-3; and especially the compound in column 5, lines 9-10) each teach thiazole compounds that are either structurally the same as (see above 102 rejection) or structurally similar to the instant claimed compounds.

***Ascertainment of the difference between the prior art and the claims
(MPEP §2141.02)***

The difference between some of the compounds of the prior art and the compounds instantly claimed is that the instant claimed compounds are generically described in the prior art.

***Finding of prima facie obviousness--rational and motivation (MPEP
§2142-2413)***

The indiscriminate selection of "some" among "many" is *prima facie* obvious, In re Lemin, 141 USPQ 814 (C.C.P.A. 1964). The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity (e.g., treating asthma).

One skilled in the art would thus be motivated to prepare products embraced by the prior art to arrive at the instant claimed products with the expectation of obtaining additional beneficial products which would be useful in treating, for example, asthma. Since Oballa et al. (pages 2 and 35) and Pick et al. (column 1, lines 16-53) both teach thiazole compounds that are structurally similar to each other and are both useful in treating asthma, the combination of Oballa et al. and Pick et al. would also teach and suggest the instant claimed invention. The instant claimed invention would have been suggested to one skilled in

the art and therefore, the instant claimed invention would have been obvious to one skilled in the art.

Response to Arguments

Applicant's arguments filed January 14, 2009, and a duplicate on March 4, 2009, have been fully considered but they are not persuasive. Applicant argues that generic formula I in Oballa et al. does not provide compounds with a thiazoyl-biphenyl substituent. Applicant argues that Pick et al. do not teach the instant claimed thiazole compounds since the instant R¹ variable in the instant claimed invention cannot represent C(O)NH₂ or CNOHNH₂. Applicant concludes that there is no teaching or suggestion in either of the references for treating pain.

All of Applicant's arguments have been considered but have not been found persuasive. Applicant argues that generic formula I in Oballa et al. does not provide compounds with a thiazoyl-biphenyl substituent.

Applicant's attention is directed to pages 118, 120, 122, 125 and 126 of Oballa et al. where thiazoyl-biphenyl substituents are taught {i.e., AI1 and BI16; and AII1 and BII3} as being embraced by Formula I of Oballa et al.

Further, it is disagreed that the instant R^1 variable in the instant claimed invention cannot represent $C(O)NH_2$ as found attached to the 2-position of the thiazole compounds of Pick et al. See in currently amended instant claim 1, the tenth substituent listed {i.e., $CONR^aR^b$ wherein R^a and R^b are each hydrogen} in the "(k)" definition of the instant R^1 variable. Also see the substituents in the R^1 position in the instant claims such as three of the four compounds listed in instant claim 9; the third compound listed in instant claim 10; the second compound listed in instant claim 11; and the third compound listed in instant claim 12; etc. Therefore, Applicant's argument is not persuasive.

Additionally, there is no requirement that the prior art must suggest that the claimed product will have the same or similar utility as that discovered by applicant in order to support a legal conclusion of obviousness. In re Dillon, 16 U.S.P.Q. 2d 1897, 1904 (Fed. Cir. 1990). For all the reasons given above, the rejection is deemed proper and therefore, the rejection is maintained.

Allowable Subject Matter

Claim 3 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 11 and 12 are allowed over the art of record.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

This application contains claims 19-31 drawn to an invention nonelected with traverse in the reply filed on August 18, 2008. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura L. Stockton whose telephone number is (571) 272-0710. The examiner can normally be reached on Monday-Friday from 6:15 am to 2:45 pm. If the examiner is out of the Office, the examiner's supervisor, Joseph McKane, can be reached on (571) 272-0699.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the

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automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

The Official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

/Laura L. Stockton/

Laura L. Stockton

Primary Examiner, Art Unit 1626

Work Group 1620

Technology Center 1600

January 5, 2010